REMARKS

Claims 1, 8, 9, 20, 22, 24-26, 29-31, 45, 46, 48, 51, 53, 68, 70, 74, 76, 84, 89 and 95 were pending in the instant application. Claims 1, 8, 9, 53, 68, 70, 74, 76, 84 and 89 were withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants herein. Claims 20, 22, 24-26, 30, 31, 45, 48, 51 and 95 have been rejected. Claims 29 and 46 have been objected to. Claims 20, 24, 25, 26, 30, 31, 45, 48 and 95 have been amended. Claim 22 has been canceled. New claims 96 and 97 have been added. Support for these amendments is provided in canceled claim 22 and in the specification at page 25, page 35, page 41 and Example 5. No new matter has been added. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Election/Restriction

In accordance with the Telephone Interview conducted on 9/21/07, Applicants elected Group III, rejoined with Group IV. Withdrawn from consideration are claims 1, 8, 9, 53, 68, 70, 74, 76, 84 and 89. Applicants have canceled without prejudice these claims. Applicants reserve the right to file a divisional application to this subject matter.

II. Objection of Claims 29 and 46

Claims 29 and 46 have been objected to for being dependent upon rejected claims. The Examiner has

acknowledged that these claims would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims.

It is respectfully pointed out, however, that the independent claims have been amended in a manner believed to overcome all pending rejections. Accordingly, this objection is now moot.

Withdrawal is therefore respectfully requested.

III. Rejection of Claim 45 under 35 U.S.C. 101

Claim 45 has been rejected under 35 U.S.C. 101 as the Examiner suggests that the claim as written does not sufficiently distinguish over cells that naturally exist.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 45 to be drawn to an isolated cell.

Withdrawal of this rejection is therefore respectfully requested.

IV. Rejection of Claim 30 under 35 U.S.C. 112, first paragraph - Written Description

Claim 30 has been rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. The Examiner suggests that the claims are inclusive of a genus of antibodies that compete for binding to the same epitope as the epitope bound by the monoclonal antibody produced by a hybridoma selected from the group

consisting of ATCC accession number PTA-5877 and PTA-5876. The Examiner suggests, however that the specification does not identify specific epitopes bound by the monoclonal antibodies produced by the hybridomas of ATCC accession number PTA-5877 or PTA-5876. The Examiner also suggests that the specification does not disclose and the art does not teach a genus of antibodies that compete for binding to the same epitope as the epitope bound by the monoclonal antibody produced by a hybridoma selected from the group consisting of ATCC accession number PTA-5877 and PTA-5876.

Applicants respectfully traverse this rejection.

Applicants respectfully disagree with Examiner's suggestions that the specification does not teach a genus of antibodies that compete for binding to the same epitope as the epitope bound by the monoclonal antibody produced by the hybridoma selected from the group consisting of ATCC accession numbers PTA-5877 and PTA-5876. Example 2 of the instant application describes checkerboard ELISAs conducted with the antibodies described in Example 1. The checkerboard ELISAs data in the tables of Example 2 demonstrate many antibodies have low signal to noise ratios when paired with A9 (PTA-5877) or A46 (PTA-5876) indicating these antibodies compete for binding to the same epitope as bound by A9 (PTA-5877) or A46 (PTA-5876). A graphical representation of these data is depicted in Figure 1 of the instant application.

Further, in addition to these examples, the specification teaches one of skill in the art how to identify and screen for antibodies which compete for binding to the same epitope as the epitope bound by antibodies of the present invention. See page 26 line 23 through page 28 line 29, and page 60 line 30 through page 61 line 22 of the instant application.

Accordingly, the instant specification clearly describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Further, the specification as originally filed clearly supports the claimed invention. Thus, the instant specification meets the written description requirement of 35 U.S.C. 112, first paragraph. See MPEP 2163.

Withdrawal of this rejection is therefore respectfully requested.

V. Rejection of Claims 20, 24, 26, 31, 45, 48 and 51 under 35 U.S.C. 102(b)

Claims 20, 24, 26, 31, 45, 48 and 51 have been rejected under 35 U.S.C. 102(b) as being anticipated by Soppet and Dillon (U.S. Patent 5,861,494). The Examiner suggests that Soppet and Dillon refer to Cln101 as SEQ ID NO:2 and teach a kit comprising an isolated Cln101 antibody, generated

against the full sequence or a partial sequence of Cln101, that binds to mammalian Cln101 in vivo and in vitro.

Applicants respectfully traverse this rejection.

It is respectfully pointed out that claim 20 has been amended to recite a kit comprising a suitable assay for measuring Cln101 levels and a suitable assay for measuring CA125 levels wherein the levels of both Cln101 and CA125 are determined. Support for this amendment is provided in claim 22, which has been canceled in light of this amendment. Soppet and Dillon do not teach a kit which determines levels of both Cln101 and CA125. Accordingly, this reference cannot anticipate claim 20 as amended. See MPEP 2131.

Further, claims 24, 26, 31, 45, 48 and 51 have been amended to depend from claim 30, which the Examiner has not included in this rejection and which is not anticipated by Soppet and Dillon.

Withdrawal of this rejection is therefore respectfully requested.

VI. Rejection of Claims 20, 24, 26, 31, 45, 48, 51 and 95 under 35 U.S.C. 102(e)

Claims 20, 24, 26, 31, 45, 48, 51 and 95 have been rejected under 35 U.S.C. 102(e) as being anticipated by Schlegel et al. (US 2003/0108963). The Examiner suggests that Schlegel refers to Cln101 as "REG-IV" and teaches a kit

comprising an isolated Cln101 antibody that binds to mammalian Cln101 in vivo or in vitro.

Applicants respectfully traverse this rejection.

It is respectfully pointed out that claim 20 has been amended to recite a kit comprising a suitable assay for measuring Cln101 levels and a suitable assay for measuring CA125 levels wherein the levels of both Cln101 and CA125 are determined. Support for this amendment is provided in claim 22, which has been canceled in light of this amendment. Schlegel et al. do not teach a kit which determines levels of both Cln101 and CA125. Accordingly, this reference cannot anticipate claim 20 as amended. See MPEP 2131.

Further, claims 24, 26, 31, 45, 48, 51 and 95 have been amended to depend from claim 30, which the Examiner has not included in this rejection and which is not anticipated by Schlegel et al.

Withdrawal of this rejection is therefore respectfully requested.

VII. Rejection of Claims 20 and 22 under 35 U.S.C. 103(a)

Claims 20 and 22 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Soppet and Dillon (U.S. Patent 5,861,494) as applied to claim 20 above, and further in view of Sakamoto (Gut, March 1987, 28:323-329). The Examiner has acknowledged that Soppet and Dillon do not teach a kit for diagnosing a patient's susceptibility to

ovarian cancer comprising a suitable assay for measuring Cln101 levels wherein the levels of Cln101 are determined, further comprising a suitable assay for measuring CA125 levels wherein the levels of both CA125 and Cln101 are determined. However the Examiner suggests that the deficiencies are made up in the teachings of Sakamoto.

Applicants respectfully traverse this rejection.

Claim 22 has been canceled and claim 20 has been amended to include the limitations of claim 22.

Applicants respectfully disagree with the Examiner's interpretation of Sakamoto et al. and find comments in the Office Action relating to Sakamoto et al. misleading.

For example, in the Office Action, the Examiner suggests that both Soppet and Dillon and Sakamoto et al. teach methods for diagnosing metastatic colon cancer, and therefore one would be motivated to combine these references. The Examiner suggests that Sakamoto et al. teach combining detection of CA125 with detection of other markers yielded higher sensitivities than by using a single marker, indicating page 328 in particular.

It is respectfully pointed however, that at page 328 Sakamoto et al. discus the false positive rates for detecting all cancers evaluated in their study (pancreatic, biliary tract, liver, colon/rectum, stomach, and esophagus), not just colon cancer. When read in context, Sakamoto et al.

goes on to discuss the results of combining markers for detection of pancreas and biliary tract cancers, not colon cancer. In fact, Sakamoto et al. do not comment at all in the results or discussion of any benefit of combining the markers evaluated for detection of colon cancer.

Accordingly, since the Examiner's comments are believed to be based upon an inaccurate interpretation of the data presented by Sakamoto et al. and go beyond the conclusions of the authors, the Examiner's suggested motivation to combine Sakamoto with Soppet and Dillon is unfounded.

Further, Applicants respectfully disagree with the Examiner's suggestion that one of skill would have a reasonable expectation for success. Colon cancer and cancers of the digestive system have different etiologies than ovarian cancer and one would not anticipate that use of markers individually in colon cancer and cancers of the digestive system would have unexpected synergistic results for detecting ovarian cancer as demonstrated in the instant application. Applicants clearly demonstrate unexpected synergistic results for combining Cln101 and CA125 to detect ovarian cancer in Example 5.

Therefore, since there is no motivation to combine Sakamoto et al. with Soppet and Dillon, and these references do not teach or suggest the unexpected synergistic results

of the instant invention, maintenance of this rejection under 35 U.S.C. 103(a) is improper.

Withdrawal of this rejection is therefore respectfully requested.

VIII. Rejection of Claims 24 and 25 under 35 U.S.C. 103(a)

Claims 24 and 25 under 35 U.S.C. 103(a) have been rejected under 35 U.S.C. 103(a) as being unpatentable over Soppet and Dillon (U.S. Patent 5,861,494) as applied to claim 24 above and further in view of Casalini et al. (Cancer Immunol. Immunother. July 1993 37:54-60). The Examiner has acknowledged that Soppet and Dillon do not specifically teach that the Cln101 antibodies would internalize upon binding to Cln101 on a mammalian cell in vivo. However, the Examiner suggests that the deficiency is made up by Casalini.

Applicants respectfully traverse this rejection.

MPEP 2143.03 and the case law are clear; if an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Claims 24 and 25 have been amended to depend from claim 30.

Neither of the cited references teach or suggest the antibody of claim 30.

Accordingly, claim 30 and claims dependent therefrom are not obvious in light of the combination of these references.

Withdrawal of this rejection is therefore respectfully requested.

IX. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

Kathleen A. Tyrrell
Reg. No. 38,350

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LICATA & TYRRELL P.C.
66 E. Main Street
Marlton, New Jersey 08053

(856) 810-1515